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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,599	02/05/2004	Andrew S. Kende	176/60813 (6-11400-728)	5421

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Edwin V. Merkel
Nixon Peabody LLP
Clinton Square, P.O. Box 31051
Rochester, NY 14603-1051

EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/772,599	Applicant(s) KENDE ET AL.	
	Examiner S. Devi, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-25 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) 18-25 ~~is/are~~ are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16 and 17 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2504</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Preliminary Amendment

- 1) Acknowledgment is made of Applicants' preliminary amendment filed 02/05/04. With this, Applicants have amended the specification.

Election

- 2) Acknowledgment is made of Applicants' election filed 07/01/04 in response to the restriction requirement mailed 05/26/04. Applicants have elected invention I, claims 16 and 17, with traverse. Applicants' traversal is on the grounds that all inventions are closely related and would require common areas of search and consideration. With regard to the species election requirement, it is noted that Applicants have not made an election of species.

Applicants' argument has been carefully considered, but is not persuasive. As clearly set forth in the restriction requirement mailed 05/26/04, the inventions belong to three different methods, which differ from one another in method steps, objectives, reagents or compositions used, and ultimate goals accomplished. The inventions are classified in different classes and/or subclasses, requiring searches that are non-coextensive. It is noted that Applicants have neither contested the patentable distinctness of various inventions, nor presented any argument showing a lack of burden on the Office for conducting multiple searches on the distinct products used in the methods. The restriction requirement set forth in the Office Action mailed 05/26/04 is proper and is maintained. The restriction requirement is hereby made FINAL. All species have been examined.

Status of Claims

- 3) Claims 1-15 and 26-34 have been canceled via the preliminary amendment filed 02/05/04. Claim 17 has been amended via the amendment filed 02/05/04. Claims 16-25 are pending. Claims 18-25 have been withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. 1.142(b) and M.P.E.P. § 821.03.

Elected claims 16 and 17 are under examination. A First Action on the Merits is issued on these claims.

Information Disclosure Statement

- 4) Acknowledgment is made Applicants' Information Disclosure Statement filed 02/05/04. The

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information referred to therein has been considered and a signed copy is attached to this Office Action.

Priority

5) The instant application is a Divisional of application SN 10/121,207 filed 04/11/02, *now US patent 6,713,059*, which is a Divisional of application SN 09/293,687, filed 04/16/1999, *now U.S. patent 6,395,282*, which claims domestic priority to the provisional application 60/082,025 filed 04/16/1998.

Title

6) The title of the invention is not descriptive. A new title reflective of elected invention --A Method for Detecting a Gram-negative Bacterial Autoinducer Molecule-- is suggested.

Specification

7) The instant specification is objected to because the amendment to the first paragraph of the specification dated 02/05/04 does not accurately reflect the issued status of the prior applications, as indicated above in italicized letters under 'Priority'.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

8) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

9) Claims 16 and 17 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claims 16 and 17 are indefinite and/or incorrect in the recitation: "a Gram negative bacteria" [Emphasis added]. See line 3 of claim 16 and line 2 of claim 17. The rejection can be obviated by changing the recitation to --a Gram negative bacterium--.

(b) Claim 16 is vague in the recitation: 'Gram negative bacteria autoinducer'. For clarity, it is suggested that Applicants replace the limitation with --a Gram negative bacterial autoinducer--.

(c) Claim 16 is vague, confusing and/or redundant in the recitation: 'an antibody in which the antibody specifically binds the autoinducer of a Gram negative bacteria'. To obviate the rejection, it is suggested that Applicants replace the limitation with --an antibody which binds

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specifically to the Gram negative bacterial autoinducer--.

(d) Claim 17 is vague, confusing and indefinite in the recitation: "the autoinducer of a Gram negative bacteria of a compound of Formula (I)", because it is unclear what are Applicants trying to include or exclude by this phrase. The metes and bounds of the recitation 'the autoinducer of a compound of Formula (I)' is not understood. Clarification is requested.

(e) Claim 17 is confusing in the recitation of various specific bacteria following the recitation: "Gram negative bacteria comprising". It is unclear whether or not Applicants desire a Markush format in the claim. If so, the Office recommends the use of the phrase "a Gram negative bacterium selected from the group consisting of *Aeromonas* ..." with the use of the conjunction "and" in the last line of the claim rather than "or" in listing species.

(f) Claim 16 is indefinite, confusing and/or incomplete, because adding an antibody to a sample does not result in a 'method for detecting' a Gram negative bacterium. A method for detecting would not be complete without a detecting or detection step.

Remarks

10) Claims 16 and 17 stand rejected.

11) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of amendments, responses or papers is (703) 872-9306.

12) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

13) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to

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Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

September, 2004


S. DEVI, PH.D.
PRIMARY EXAMINER